

CLAIMS

1. A pharmaceutical composition for oral administration comprising:
 - (i) N-tert-butyldecahydro-2-[2(R)hydroxy - 4-phenyl-3-(S)-[[N-(2-quinolylcarbonyl) -L-asparaginyl]amine]butyl]-(4aS,8aS)-isoquinolone-3(S)-carboxamide (saquinavir), or its pharmaceutical acceptable salts as the active ingredient;
 - 10 (ii) a long chain fatty acid of C₁₂₋₁₈,
 - (iii) at least an alcohol of chain C₂₋₄;
 - (iv) a non-ionic surfactant;
 - (v) a pharmaceutical acceptable antioxidant
- 15 2. Pharmaceutical composition in accordance with claim 1, characterized by comprising N-tert-butyldecahydro-2-[2(R)hydroxy - 4-phenyl-3-(S)-[[N-(2-quinolylcarbonyl) -L-asparaginyl]amine]butyl]-(4aS,8aS)-isoquinolone-3(S)-carboxamide (saquinavir), or its pharmaceutical acceptable salts, in a concentration ranging from 10% to 80% in weight of the final composition;
- 20 3. Pharmaceutical composition in accordance with claim 2, characterized by comprising N-tert-butyldecahydro-2-[2(R)hydroxy - 4-phenyl-3-(S)-[[N-(2-quinolylcarbonyl) -L-asparaginyl]amine]butyl]-(4aS,8aS)-isoquinolone-3(S)-carboxamide (saquinavir), or its pharmaceutical acceptable salts, in a concentration ranging from 15% to 70% in weight of the final composition;
- 25 4. Pharmaceutical composition of claim 1, characterized by comprising a fatty acid of C₁₂₋₁₈ in a concentration

- ranging from 20% to 80% in weight of the final composition;
5. Pharmaceutical composition of claim 4, characterized by the fatty acid of C₁₂₋₁₈ is preferably oleic acid, used in a concentration ranging from 20% to 70% in weight if the final composition;
10. Pharmaceutical composition if claim 1, characterized by using an alcohol of C₂₋₄, being this alcohol preferably ethanol, or propylene glycol and or mixtures between them, preferably in a concentration ranging from 2% to 20% in weight of the final composition;
15. Pharmaceutical composition of claim 1, characterized by comprising a non-ionic surfactant selected among polyethoxylated derivatives from castor oil and the polyoxyethylene sorbitan esters (polysorbates) in a concentration ranging from 0.1% to 30% in weight of the final composition;
20. Pharmaceutical composition of claim 7, characterized by comprising among polyethoxylated derivatives from castor oil preferably the polyethoxylated castor oil 35 (Cremophor EL) and or polyethoxylated hydrogenated castor oil 40 (Cremophor RH 40), in a concentration ranging from 0.1% to 30% in weight of the final composition;
25. Pharmaceutical composition of claim 7, characterized by comprising among the polyoxyethylene sorbitan esters preferably the liquid polysorbates like polissorbate 20, 40, 60 and 80, in a concentration ranging from 0.1% to 30% in weight of the final composition;
- 30.

10. Pharmaceutical composition according to claim 1, characterized by comprising a pharmaceutical acceptable antioxidant selected from alpha-tocopherol and butylated hidroxytoluene, in a concentration ranging from 0.001 % to 2.0% in weight of the final composition;
11. Pharmaceutical composition according to claims 1 to 10, characterized by consisting of a stable concentrate microemulsion wherein the active ingredient N-tert-butyldecahydro-2-[2(R)hydroxy - 4-phenyl-3-(S)-[[N- (2- quinolylcarbonyl) -L-asparaginyl]amine]butyl]- (4aS,8aS)-isoquinolone-3(S)-carboxamide (saquinavir), or its pharmaceutical acceptable salts, is soluble;
12. Pharmaceutical composition according to claim 11, characterized by being fractionated in single doses in the form of soft gelatin capsules or in the form of hard gelatin capsules for oral administration in the treatment of AIDS;
13. Pharmaceutical composition according to claim 12, characterized by being preferably fractionated in single doses in the form of soft gelatin capsules for oral administration in the treatment of AIDS;
14. Pharmaceutical composition according to claims 1 to 13 in which the bioavailability of the active ingredient, when measured by AUC and C_{max} parameters, is at least 5 times higher than the same dosage from the reference composition.
15. A process for preparing a pharmaceutical composition which comprises the following steps:
 - (a) Completely dissolving of N-tert-butyldecahydro-2-[2(R)hydroxy - 4-phenyl-3-(S)-[[N- (2-

quinolylcarbonyl) -L- asparaginyl]amine]butyl]-
(4aS,8aS)-isoquinolone-3(S)-carboxamide , or its
pharmaceutical acceptable salt, in a sufficient
amount of the alcohol of C₂-4 under controlled
temperature;

- (b) Eliminating particles by filtration;

(c) Adding the fatty acid of chain C₁₂₋₁₈, the antioxidant and the surfactant in an appropriate amount used in the composition;

10 (d) Evaporating the alcohol at a maximum temperature of 50°C under reduced pressure;

(e) Optionally, adding the surfactant from step (c) after the evaporation of the alcohol from step (d);

15 (f) Adding the alcohol C₂₋₄ under stirring and in an enough amount to complete the adequate weight of the final composition

16. Process according with claim 15, characterized by comprising in step (a) the compound N-tert-butyldecahydro-2-[2(R)hydroxy - 4-phenyl-3-(S)-[(N-(2- quinolylcarbonyl) -L- asparaginyl]amine]butyl]- (4aS,8aS)-isoquinolone-3(S)-carboxamide (saquinavir), or its pharmaceutical acceptable salts, in the crystalline, amorphous, micronized or mixtures of that forms, in a concentration ranging from 0.01% to 90% in weight of the final solution;

20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100 105 110 115 120 125 130 135 140 145 150 155 160 165 170 175 180 185 190 195 200 205 210 215 220 225 230 235 240 245 250 255 260 265 270 275 280 285 290 295 300 305 310 315 320 325 330 335 340 345 350 355 360 365 370 375 380 385 390 395 400 405 410 415 420 425 430 435 440 445 450 455 460 465 470 475 480 485 490 495 500 505 510 515 520 525 530 535 540 545 550 555 560 565 570 575 580 585 590 595 600 605 610 615 620 625 630 635 640 645 650 655 660 665 670 675 680 685 690 695 700 705 710 715 720 725 730 735 740 745 750 755 760 765 770 775 780 785 790 795 800 805 810 815 820 825 830 835 840 845 850 855 860 865 870 875 880 885 890 895 900 905 910 915 920 925 930 935 940 945 950 955 960 965 970 975 980 985 990 995 1000 1005 1010 1015 1020 1025 1030 1035 1040 1045 1050 1055 1060 1065 1070 1075 1080 1085 1090 1095 1100 1105 1110 1115 1120 1125 1130 1135 1140 1145 1150 1155 1160 1165 1170 1175 1180 1185 1190 1195 1200 1205 1210 1215 1220 1225 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11850 11855 11860 11865 11870 11875 11880 11885 11890 11895 119

19. Process according with claim 15, characterized by using in step (a) temperatures ranging from 20°C to 50°C;
20. Process according to claim 15, characterized by the fatty acid of chain C₁₂₋₁₈ used in step (c) is the oleic acid;
21. Process according to claim 15, characterized by the antioxidant used in step (c) is the tocopherol, or the butylated hydroxytoluene or mixtures between them;
22. Process according to claim 15, characterized by the non-ionic surfactant used in step (c) or (e) is the polyethoxylated castor oil 35 (Cremophor EL) or the polyethoxylated hydrogenated castor oil 40 (Cremophor RH 40);
23. Process according to claim 15, characterized by using in steps (c) or (e) the polyoxyethylene sorbitan esters, preferably the liquid polysorbates as polyssorbate 20, 40, 60 and 80;
24. Process according to claim 15, characterized by in step (d) the maximum temperature used for the evaporation of the alcohol of chain C₂₋₄ is 50°C;
25. Process according to claim 15, characterized by the alcohol of chain C₂₋₄ used in step (f) is the ethanol, or propyleneglycol, or mixtures between them;
26. Process according to claim 15, characterized by the resulting product presents N-tert-butyldecahydro-2-[2(R)hydroxy - 4-phenyl-3-(S)-[[N-(2-quinolylcarbonyl) -L- asparaginyl]amine]butyl]-(4aS,8aS)-isoquinolone-3(S)-carboxamide (saquinavir) or its pharmaceutical acceptable salts, in a

concentration ranging from 10% to 80% in weight of the final pharmaceutical composition;

27. Process according to claim 26, characterized by the resulting product contains the compound N-tert-butyldecahydro-2-[2(R)hydroxy - 4-phenyl-3-(S)-[[N-(2-quinolylcarbonyl) -L- asparaginyl]amine]butyl]- (4aS,8aS)-isoquinolone-3(S)-carboxamide (saquinavir), or its pharmaceutical acceptable salts in a concentration preferably ranging from 15% to 70% in weight of the final pharmaceutical composition;
- 10 28. Process according to claim 15, characterized by the resulting product contains the fatty acid of chain C₁₂₋₁₈ in a concentration ranging from 20% to 80% in weight of the final pharmaceutical composition;
- 15 29. Process according to claim 28, characterized by the resulting product contains the oleic acid as the fatty acid of chain C₁₂₋₁₈, in a concentration ranging preferably from 20% to 70% in weight of the final pharmaceutical composition;
- 20 30. Process according to claim 15, characterized by the resulting product contains the ethanol, or propyleneglycol or mixtures of them as the alcohol of chain C₂₋₄, in a concentration ranging from 2.0% to 20% in weight of the final pharmaceutical composition;
- 25 31. Process according to claim 15, characterized by the resulting product contains as the non-ionic surfactant the poliethoxylated ethers of castor oil, or the polyoxyethylene sorbitan esters (polysorbates), in a concentration ranging from 0.1% to 30% in weight of the final pharmaceutical composition;
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32. Process according to claim 31, characterized by the resulting product contains preferably the polyethoxylated castor oil 35 (Cremophor 35) and/or polyethoxylated hydrogenated castor oil 40 (Cremophor RH 40) as the non-ionic surfactant the polyethoxylated derivatives of castor oil, in a concentration ranging from 0.1% to 30% in weight of the final pharmaceutical composition;
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33. Process according to claim 31, characterized by the resulting product contains as the non-ionic surfactant, the polyoxyethylene sorbitan esters (polysorbates), the liquid polysorbates like polyssorbate 20, 40, 60 or 80, in a concentration ranging from 0.1% to 20% in weight in the final pharmaceutical composition;
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34. Process according to claim 15, characterized by the resulting product contains the alpha-tocopherol or the butylated hydroxytoluene as the antioxidant, in a concentration ranging from 0.001% to 2.0% in weight of the final pharmaceutical composition;
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35. Process according to claim 15, characterized by furnishing a stable concentrate microemulsion wherein the active ingredient is soluble, and which is suitable for being encapsulated in hard or soft gelatin capsules for the oral administration in AIDS treatment.
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36. A method to increase bioavailability of N-tert-butyldecahydro-2-[2(R)hydroxy - 4-phenyl-3-(S)-[[N-(2-quinolylcarbonyl) -L- asparaginyl]amine]butyl]-(4aS,8aS)-isoquinolone-3(S)-carboxamide (saquinavir), or its pharmaceutical acceptable salts, which consists in administering to a patient during the
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therapy a pharmaceutical composition prepared according to claims 15 to 36.